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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,124	01/12/2004	Andrew L. Abrams	MICRODOSE 99.02 CON2	3144

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 04/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/756,124	ABRAMS ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-12 is/are rejected.

7)☒ Claim(s) 13-20 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 01/12/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Preliminary Amendment and Information Disclosure Statement filed 01/12/04, and Change of Address filed 12/27/04.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. It appears from the specification that the ingestible membrane is critical or essential to the practice of the invention, but not included in the claims is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). See Figs. 1-6, and specification, for example page 9, lines 14-20, page 11, lines 8-21, and pages 13-14.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3-12 recite the limitation "said membrane" or "the membrane". There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not recite the limitation "membrane".

Claim 9 is indefinite in the use of the phrase "wherein said membrane is formed into a tablet or capsule". Could it mean the delivery package is formed into a tablet or capsule, since the membrane itself does not appear to form into a tablet or a capsule per se? Further clarification is suggested.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 and 11-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,702,683 ('683). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '683 patent claims a controlled release pharmaceutical delivery package comprising two or more different active

pharmaceuticals combined in a single delivery package, segregated from one another, electrostatically deposited on a porous, permeable or semi-permeable ingestible membrane, and formed into a tablet, wherein said two or more active pharmaceuticals comprise combinations of pharmaceuticals selected from the group consisting of (a) Ketoconazole and testosterone, (b) Valacylovir and one or both of Cimetidine and Probenecid, (c) Enalapril and a beta adrenergic-blocking agent, methyldopa, nitrate, a calcium blocking agent, hydrazinc, Prazosin or Digoxin, (d) Omeprazole and B12, (e) Omeprazole and Clarithoromycin, (f) Tamoxifen and a diuretic, (g) Isotretinoin and an oral contraceptive, and (h) Metformin HCl and Solfonylurea. Membrane comprises alkali-dissolvable or acid-dissolvable material is found in claim 2. The adhesive on the outer surfaces of the membrane is found in claims 5-7. Inert coating is found in claim 9.

Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,428,809 ('809). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '809 claims a pharmaceutical delivery package comprising fixed unit dose quantities of two or more different active pharmaceutical ingredients (a) combined in a single delivery package, and (b) segregated from one another within said package. The active ingredients are segregated from one another in a compartmentalized capsule is found in claim 2. The pharmaceuticals are segregated from one another in a tablet is found in claim 3. Inert coatings are found in claim 4. Active ingredients are found in claims 5-7 and 9-12

The wordings are not exactly the same, however, both patents '683 and '809 claimed similar subject matter, *e.g.*, a pharmaceutical delivery package suitable for two or more different active ingredients segregated from one another. There are no unusual and/or unexpected results which would rebut prima facie obvious. As such, the instant claims would have been obvious given the claims of patent '683 or '809, which set out a similar delivery package.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4 and 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Depui et al. WO 97/25065.

Depui discloses a pharmaceutical dosage form comprising an enteric coated proton pump inhibitor and one or more prokinetic agents in a fixed formulation in the form of multilayer tablets, capsules (see abstract; and page 6). The dosage form can be covered with a film forming agent (page 20, lines 4-11). Proton inhibitor layer and the prokinetic agents layer are separated by an anti-tacking layer (page 20, lines 20-24).

Claims 1-3, 8, 9 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Barry et al. US 5,055,306.

Barry discloses a sustained release formulation comprising a core comprising a predetermined amount of one or more active substances, and a coating covering the whole surface of the core comprising water swellable polymer (see abstract; and column 3, lines 36-68). The coated core granules are compressed into tablet (column 4, lines 1-5; and column 7, lines 47-65).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sturzenegger et al. US 4,197,289.

Sturzenegger teaches a sustained release pharmaceutical dosage form comprising edible web having two or more medicaments electrostatically deposited onto the web that is self destructs or degradable in body fluids or enzymes (see abstract, columns 6-8, and columns 24-26). Before the deposit of the medicaments, the web can be coated with an adhesive layer (column 17, lines 5-41). The web can be processed into separate tablet layers, capsules, dragees, or suppositories (column 3, lines 38-41; and column 4, lines 58-60).

Sturzenegger does not expressly teach the fixed unit dose quantities of the medicaments. However, the advantageous results over the dosage form includes the exactness of the preparation of a solid dosage forms, such as uniform in size, shape, release rate, and the like (column 4, lines 33-40; and column 16, lines 40-44). Thus, it would have been obvious for one of ordinary skill in the art to, by routine experimentation modify the dosage form of Sturzenegger to obtain a unit dosage form with a fixed quantities of drugs, because Sturzengger teaches the exact and uniform deposition of the active ingredient on the web (column 11, lines 1-5), because Sturzenegger teaches the amount of active ingredient loaded can be determined by transmission spectrophotometry (column 12, lines 46-56), and because Sturzenegger teaches the advantageous results of a single dosage form containing two or more medicaments being separated by edible membrane.

Claims 1-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sturzenegger et al. US 4,197,289, and Digenis US 5,672,359.

Sturzenegger is relied upon for the reason stated above. Sturzenegger does not explicitly teach the compartmentalized capsule.

Digenis teaches a controlled release capsule comprising three or more distinct compartments, each compartment comprising at least one drug (see abstract; column 4, lines 49-67). The capsule comprises combination of drugs (column 5, lines 13-15). Thus, it would have been obvious for one of ordinary skill in the art to modify the capsule of Sturzenegger using the multi-compartment capsule in view of the teaching of

Digenis, because Sturzenegger teaches the desirability of achieving a delivery system containing two or more drug, and because Digenis teaches the use of multi-compartment capsule useful to provide an immediate and sustained mode of release of combination of drugs (column 1, lines 8-16; and column 5, lines 13-16).

Claims 1-9, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sturzenegger et al. US 4,197,289, and Digenis US 5,672,359.

Sturzenegger is relied upon for the reason stated above. Sturzenegger does not explicitly teach the layer tablet.

Depui discloses a pharmaceutical dosage form comprising an enteric coated proton pump inhibitor and one or more prokinetic agents in a fixed formulation in the form of multilayer tablets, wherein the two active agents are separated by an anti-tacking layer (page 20, lines 20-24). Thus, it would have been obvious for one of ordinary skill in the art to modify the composition of Sturzenegger using the multilayer tablet in view of the teaching of Depui, because Sturzenegger teaches the desirability of achieving a delivery system containing two or more drug, and because Depui teaches the use of multilayer tablet containing combination of drugs that sill simplify the regimen and improve the patient compliance.

Claims Allowable

Claims 13-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Pertinent Arts

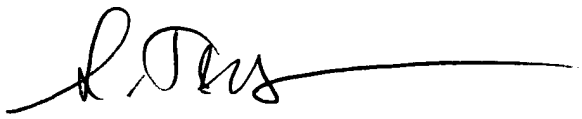
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kay, Sivaramakrishnan et al., Kurihara et al., and Abrams et al. are cited as being of interest for the teachings of multi-compartment capsule and/or multilayer tablet.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Susan T. Tran
Examiner
Art Unit 1615